



EMERGENCY RESPONSE PLAN

OCTOBER 2016

CUSTOMED, INC. Fajardo, Puerto Rico

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EMERGENCY RESPONSE PLAN

Rule #107: Air Pollution Emergencies, of the PR-Regulations for the Control of the Atmospheric Pollution



Prepared for:

CUSTOMED, INC.

FAJARDO, PR

OCTOBER 2016



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- FAJARDO Government Agencies:
 - PR-Police Department: (787) 863-2020 & #911
 - PR-Fire Department: (787) 863-2330
- Local Government Agencies:
 - Environmental Quality Board: (787) 767-8181
 Ambient Emergency: Ext. 3228, 3231, 3248, 6141
 - Medical Center Air Ambulance: (787) 756-3424
 - PR-Health Department: (787) 756-2412, 756-2452
 - PR-Industrial Hospital: (787) 754-2525
 - Poison Control Center: 1-800-222-1222
 - State Emergency & Disaster
 Management Agency: (787) 724-0124 & (787) 863-1502
- Local Contractors:
 - Clean Harbors Caribe: (787) 641-5393 & (787) 413-1943
 - Central Alarms: (787) 786-9812
- Federal Government Agencies:
 - National Response Center: 1-800-424-8802
 - US Environmental Protection Agency, CFO: (787) 977-5870

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4.) Check List for Accepting EtO-Cylinders

5.) Ambient Sampling in Manufacturing Areas

6.) Preventive Maintenance for Dry Vacuum Pump

7.) Preventive Maintenance for Scrubber System

8.) Preventive Maintenance for Aeration Room

9.) Master Calibration List & Schedule for Sterilizer

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11.) Record of Diesel Oil Monthly Consumption¹

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13.) Check Procedure for Receiving/Unloading Diesel Oil

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Appendix J:

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¹ This form was not available in the previous "Emergency Response Plan – December 2010".



SECTION I: INTRODUCTION

1.1 Applicability

The PR-Environmental Quality Board (EQB) enforces the Rule 107: Air Pollution Emergencies, through the PR-Regulations for the Control of Atmospheric Pollution. The objective is to prevent the emission or excessive buildup of air pollutants during malfunction or emergency episodes.

According to the Rule 107, any source that may release, leak or emit toxic or hazardous substances into the ambient air has to prepare and submit to the EQB, an *Emergency Response Plan (ER-Plan)*. The Plan should discuss the preventing measures that the source owner/operator will implement to avoid the occurrence of an emergency, due to the effects of these substances on the health of persons. The Plan should also provide requirements for accident prevention and emergency response.

Once the ER-Plan is approved by the EQB, it should be accessible to all concerned and all involved personnel in emergency response duties.

Appendix A provides a copy of the Rule 107. Appendix B provides a list of some environmental definitions used by the EQB, the US Environmental Protection Agency (EPA) and the National Institute of Occupational Safety and Health (NIOSH).

1.2 Facility Description

CUSTOMED, INC. is near the intersection of PR-Road #3 and #7 Igualdad Street, in the Municipality of Fajardo, PR. Figure #1 is a location map of this facility. CUSTOMED employs approximately 50 persons at the site. The physical facility consists of four buildings. Figure #2 is a layout plan of the facility.

The Rule 107 (C) (2) (a/b) requires the following information:

1.2.a) Source Name: CUSTOMED, INC.

Location Address: Calle Igualdad #7

Fajardo, Puerto Rico 00738

Postal Address: Calle Igualdad #7

Fajardo, Puerto Rico 00738

1.2.b) Facility Operator: Mr. Elvin Almodóvar

Title: General Manager

Telephone: (787) 548-9342 Fax: (787) 860-2518



1.3 Distribution of the Emergency Response Plan (ER-Plan)

CUSTOMED, INC. has prepared the ER-Plan to all concerned personnel. A copy of the ER-Plan will be available for on site review during normal working hours.

The following personnel of CUSTOMED, INC. will be provided with a copy of the approved ER-Plan:

- Plant Manager,
- Operation Manage,
- Warehouse Manager, and
- Safety Manager

Since CUSTOMED does not participate in any Local Emergency Planning Committee (LEPC), a copy of our ER-Plan will be forward to the Fajardo City Hall, and any government agency that requests a copy, too.

On October 03, 2016 we sent a letter to the Hospital HIMA/San Pablo in Fajardo; see Appendix C. The objective is to determine the hospital capability to deal with emergency episodes where releases, leaks or emissions of Ethylene Oxide (ETO) and Diesel Oil may affect the health of our plant operators as a result as our daily operations. At this time we have not yet received any reply.

1.4 Requirements for Updating the ER-Plan

The ER-Plan will be amended whenever a change in the facility affects the potential for any incidental release, leak or spill of Diesel Oil and/or ETO. The Plan may also be amended whenever occur a substitution in the Emergency Response Coordinators and/or Emergency Response Team. The EQB will be informed of such up-dating requirements.



SECTION II: HAZARDOUS SUBSTANCE

The Rule 107 (C) (2), Section (c) of the EQB regulation, requires to CUSTOMED the identification of possible sources that may cause incidental releases of hazardous substances during the manufacturing activity.

2.1 Affected Sources of the Manufacturing Activity

CUSTOMED manufacturing operations consist of the process of assembling and sterilizing convenience kits/packs for surgical and nursing procedures. The affected sources that may release, leak or emit hazardous substances are the following:

Source Descriptions

- A. The Sterilization Manufacturing Process, and
- B. The Storage of Fuel Oil & ETO-Cylinders

CUSTOMED sterilization process has now been limited to a maximum annual consumption of 9.0 Tons of *Ethylene Oxide (ETO)*. Our facility also operates several internal combustion units, which combust distillate fuel oil. According to the EQB permit authorization, the maximum sulfur content in the fuel oil is 0.05%.

The Rule 107 (C) (2), Section (d) of the EQB regulation, requires an estimate of the amount and type of substances that may be released during an emergency episode.

2.2 Releases of Hazardous Substances

The type and amount of hazardous substances that may be emitted, released or leaked are the following:

TABLE #1 - Releases of Hazardous Substances

	Source	Type of Substance	Amount of Substance
A.	One Sterilization Chamber	Ethylene Oxide	60 lbs
B.	A 5,000 gal. Diesel Tank	Diesel Oil	4,500 gal
C.	One of Four ETO Storage Cylinders	Ethylene Oxide	400 lbs



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The following are some synonyms, trade names and physical description of the hazardous substances of concern:

A. Ethylene Oxide:

Synonyms:

- EO, EtO

1-2 Epoxy ethane, Dimethylene OxideOxane, Alkene Oxide, Oxacyclopropane

- $\alpha \beta$ - Oxidoethane

Hazardousness Description:

Highly reactive and fatal if inhaled. May cause delayed lung injury, respiratory system and nervous system damage. Extremely flammable

liquid and gas under pressure.

Physical Description:

Colorless liquid or gas, sp. gr. 0.887 @7/4 °C, a "sweet" gas with olefinic or ether-like odor

Incompatibility/Reactivity:

Very Reactive. Runaway exothermic polymerization reactions can result from contamination with amines, ammonia, water, acids/bases, metal chlorides, oxidizers

Vapor Pressure, @ 68 °F:

1,094 mm Hg

Boiling Point:

50.9 °F

Freezing Point:

-233.1 °F

Ethylene Oxide has a Time-Weighted Average (TWA – 8 Hrs.) value of 1.0 ppm and a Short-Term Exposure Limit (STEL) value of 5.0 ppm (15 minutes). It is Immediately Dangerous to Life or Health (IDLH) in concentrations of 800 ppm or more.



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B. Diesel Oil:

Synonyms:

- Low Sulfur Diesel

Diesel Fuel #2

Hazardousness Description:

Flammable Liquid Substance, for general

purpose domestic heating, for use in burners

not requiring No. 1 fuel oil.

CAS No:

68475-34-6

Flash Point:

125 °F minimum PMCC

Pour Point:

20 °F

Saybolt Viscosity:

32.6 sec. (Universal at 100 °F)

Gravity:

30 °API

Max. Distillation Temp:

640 °F

Min. Distillation Temp:

540 °F

Appendixes D and E provides copies of the Material Safety Data Sheets of these hazardous substances.



SECTION III: PREVENTIVE & COUNTER MEASURES

The Rule 107 (C) (2) (e), requires details of our actual prevention and counter measures to avoid incidental or unexpected hazardous air emissions.

3.1 Description of the Preventive & Counter Measures

CUSTOMED operates several sources that actually vent hazardous substance of Ethylene Oxide² (CH₂)₂O; CAS-RN #75-21-8.

CUSTOMED operates in the plant several preventing and counter measures, which also reduce incidents of ETO releases/leaks. The following provides a detail of the affected sources and their actual prevention and counter measures to prevent hazardous emissions:

3.1.1 Sterilization Chamber

The sterilization chamber has a capacity for 9 pallet racks, and it has a volume of 1,287 cubic feet. The chamber vents to an emission control device, which is the preventing and counter measure to avoid major incidental or unexpected ETO emission release.

Notice that the sterilization chamber requires an emission control device as described in Section §63.363 (b) (2), Subpart O-Ethylene Oxide Emissions Standards for Sterilization Facility, of the 40-Code of Federal Regulations, of the US-Environmental Protection Agency (EPA).

An Acid-Water Packed Venturi-Scrubber is the emission control device of the sterilization chamber. Several performance tests have been accomplished at the stack of scrubber, during the last two (2) years. The EQB officers have witnessed all of them. The scrubber has showed compliance with the 99% ETO emission reduction, as requires Section §63.362 (c) –Standard for Sterilization Chamber Vent at Sources Using 1 Ton, Subpart O.

3.1.2 Aeration Room

Once the sterilization process finished, the material coming out is temporally stored in an aeration room. In the room, low concentrations of ETO are produced over long period of time, as the stored material de-gassing. The room has several internal pick-up suction points, which convey de-gassing streams (ETO fumes) to an emission control device.

² Appendix F provides some physical properties of Ethylene Oxide,



The aeration room vents to another emission control device, which is the preventing and counter measure to avoid major incidental or unexpected ETO emission release.

A Dry-Bed Oxidation System is the emission control device of the Aeration Room. Several performance tests have been accomplished at the inlet/outlet gaseous points of the system, during the last two (2) years. The EQB officers have witnessed all of them. The system has showed compliance with the maximum ETO emission concentration; e.g. a stack emission of ETO less than 1 ppm.

3.1.3 Fuel Oil Storage Tanks

The tank is above ground and it has a maximum storing capacity of 5,000 gallons. The Day Tank supply Diesel oil to a commercial steam boiler, one emergency electric power generation unit and a Fire Pump.

The following are the tanks' preventive/counter measures:

Tank Description

Available Preventive/Counter Measure

A. A Tank of 5,000 gal capacity:

1. Double Internal Walls Construction

2. Alarm:

An audible alarm is activated if the liquid level in the tank exceeds the setting during its filling up activity.

3.1.4 ETO-Cylinder Room

The ETO is received in pressurized cylinders of 400 Lbs capacity, each. As a preventive and counter measure, the cylinders are isolated in any of two rooms (the ETO-Cylinder Rooms), see Figure # 2. The rooms are closed structures with only one principal access door, each. The doors are locked at all times and a door's key procedure has been established to have access in any of the 2-rooms. The cylinder valves are here maintained at closed-position all time, except when they are going to be used. Once finished the cylinder³ in use, to operator immediately get the valve to the closed-position again.

Each ETO-Cylinder Room normally store up to 2-cylinders at any time. The cylinder replacement, valve opening and/or pipe fitting/connection is only performed by the CUSTOMED personnel.

³ Only one cylinder is in use at any time, since CUSTOMED has one sterilization chamber.



The Rule 107 (C) (2) (f), requires the schedule in the case of the construction or installation of any new or proposed prevention/counter measures. At this time, CUSTOMED do not propose any new or additional prevention/counter measures. Our actual prevention/counter measures have proved that they are very effective.



SECTION IV: INVENTORY OF EQUIPMENTS IN ETO & DIESEL OIL SERVICES

The Rule 107 (C)(2)(g) of the EQB regulation requires an inventory of the equipment, accessories, instruments, connections, process systems or other appurtenances that may emit, release or leaks toxic or hazardous substances.

The possible sources that may cause incidental emissions, releases or leaks of ETO are most likely to result of process failures or operator errors. Operator errors may include the following:

- (1) The accepting of leaking ETO-Cylinders,
- (2) The improper handling of the ETO-Cylinders, and/or
- (3) The improper handling of the "empty" ETO-Cylinders that could still have small amounts of ETO gas

Figure #2 illustrates the specific locations of (1)-the Sterilization Chamber, (2)-the Aeration Room, (3)-the 2-ETO-Cylinder Rooms and (4)-the Fuel Oil Storage Tank of 5,000 gallons capacity.

4.1 Inventory of Units in ETO Service

The equipment, accessories, instruments, connections, process system or other appurtenances that may emit, release or leak ETO is well anticipated and well defined. The following is the inventory of all units that could be in ETO service:

TABLE #2 - Inventory of Units in ETO Service

Type of Unit

Unit Description	Equipment	Accessory	Instrument	Connection	Process System	Other
Packed Venturi-Scrubber	X					
ETO-Cylinder Rooms					Χ	
ETO-Dispensing Line						Х
Scrubber Valves				Χ		
Aeration Room Blower	Х					
ETO-Cylinder Valve				Χ		
Pressure Gages		Χ				
Scrubber Side Glass			X			

4.2 Inventory of Units in Diesel Oil Service

The equipment, accessories, instruments, connections, process system or other appurtenances that may release, leak or spill Diesel Oil also is well anticipated and defined.

The following is the inventory of all the units that could be in Diesel Oil service:

TABLE #3 - Inventory of Units in Diesel Oil Service

Type of Unit

Unit Description	Equipment	Accessory	Instrument	Connection	Process System	Other
Storage Tank (5,000 gals)	Х					
Steam Boiler	Х					
Electric Power Generator	Х					
Fire Pump	Χ					
Pipe Valves				Х		
Pipe Connections				Χ		
Bulk Truck Dispensing Line		Χ				Χ
Tank Leveling Alarm			Х			4



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SECTION V: INTERNAL ADMINISTRATIVE PROCEDURES

The Rule 107 (C) (2) (h) of the EQB regulation requires a description of the internal administrative procedures for the following:

- (1) To inspect potential sources of emissions or leaks of hazardous substances, and
- (2) The current alert notification and procedure, including a notification roster and the response team members and responsibilities

As an Administrative Procedure, CUSTOMED has already installed and maintains a security alarm system with cameras that is connected to a central station. The plant also has a fence surrounds the entire buildings. These two measures prevent the access of unknown and/or unauthorized entry of persons to the property of CUSTOMED. Notice, the cameras may also alert our personnel of any abnormal condition occurring out of the ETO-Process Building and at the Diesel Tank of 5,000gals capacity.

5.1 Inspection of Units in Service with ETO and Diesel Oil

The prevention of failure of the units listed on Tables #2 and #3 requires a monthly Inspection Program.

The Program objective is to assess the condition and availability of the units in ETO service and/or in Diesel oil service. The Area Supervisors and their plant operators will conduct these inspections.

The units that operate in ETO-service are checked on a monthly base by our personnel who operate the sterilization process. The units that operate in Diesel Oil-service are checked on a monthly base by our personnel who operate our internal combustion facilities.

Appendix G provides copy of the inspection forms that are filled by CUSTOMED plant operators. A new form has been added – "Record of Diesel Oil Monthly Consumption". These forms are maintained in the facility for two (2) years. However, in the event of any incidental release/leak or spill in the amount listed in Table #1, the filled forms are maintained in the facility for at least five (5) years.

5.1.1 Field Inspection Procedure

The inspection procedure requires visual checks of the units listed on Tables #2 and #3. During the inspection, the plant operators also provide their comments abut the inspected unit.

On an annual basis, plant operators have meeting and training sessions of the operations of the equipments in ETO and Diesel oil services. During the



sessions, the operators of the sterilization chamber, steam boiler, fire pump and emergency electric power generators also have the opportunity to discuss their previous experiences with the inspected equipments.

New employees are trained during two weeks, before they may work along with equipment in service with ETO and/or Diesel Oil.

5.1.2 Emergency Turning-Off Equipments

Emergency turning-off of the sterilization chamber is automatically accomplished by the safety system of the chamber. Failure to turn off automatically the chamber, then it is manually turned-off by the experienced operators who daily work with the chamber. Notice, the experienced operators are employees who have been trained to work with the sterilization chamber. They may turn-off the chamber at the control panel.

Spills of Diesel oil could be produced while filling the 200 gals Day-Tank or the 5,000 gals Tank. These tanks are all above ground.

The Diesel filling of the Day-Tank is automatically turned-off by the safety system of the tank. Failure to turn off automatically the safety system, then it is turned-off by the experienced operators who daily work with the tank. The operators may turn-off the fuel filling line by closing off it feeding valve on the transfer line.

The Diesel tank of 5,000 gallons capacity is filled by a flexible dispensing line from a Diesel Bulk Truck. The tank filling with Diesel oil is observed by a CUSTOMED operator. Events of oil spills can be predicted, and immediately control by turning-off the valve on the dispensing line or turning-off the truck oil pump. The truck driver is responsible to accomplish this activity.

5.2 Alert Notification & Procedure

In the event our plant operators perceive a suspicious condition, find out any release/leak of ETO and/or find out a Diesel oil spill during the monthly inspections, they will inform it to the supervisor immediately. The supervisor will proceed to determine whether the ETO-release/leak or oil spill could be internally controlled and corrected with the available resources.

If the supervisor determines that the release/leak or spill is not readily controllable with the nearby resource, he (or she) will report it immediately to the Emergency Response Coordinators. The Coordinators should analyze the situation, as whether the release/leak or spill amount of hazardous substance is near the quantities listed on Table #1.



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The Coordinators should also start-up the control measures or procedures to alert and to mitigate the persisting environmental impact of the affected hazardous substance if the amount of hazardous substance could be near the quantities listed on Table #1. The Coordinators will determine when to activate Emergency Response Team to handle the situation or hire a contractor to deal with the situation.

The alert notification will be based on:

- Safety of people in the working areas,
- Safety of upwind and downwind neighbors environmental impact,
- Safety of property and materials, and
- Regulatory considerations

During an alert notification, the plant operators in the emergency area will be instructed on the action to be taken by their immediate supervisors. If the supervisors are not available, then they will be instructed by the members of the Emergency Response Team (ER-Team) who are in direct contact with the Emergency Coordinators. A roll call of employees working in the affected area must be conducted to figure out if any employee is trapped.

CUSTOMED will hire local contractors (Clean Harbor, Safety-Clean, others) to handle an emergency episode where the amount of hazardous substance is on or near the quantities listed in Table #1.

5.2.1 Emergency Response Coordinators

As a good internal policy, CUSTOMED has designated two emergency response coordinators.

The following are the names and telephone numbers of the two emergency response coordinators. They are responsible for the pollution incident prevention and control. Any of these persons will immediately be notified in case of a release/leak of ETO and a Diesel spill in the amount or near the quantities listed in Table #1.

Incident Coordinator/Commander:

Officer Name: Mr. Elvin Almodóvar

Position: Dist. Supervisor & EHS Coordinator

Office Telephone Number: (787) 622-5151 Mobil Telephone Number: (787) 548-9342

Second Incident Coordinator/Commander:

Officer Name: Mr. Héctor Agosto

Office Telephone Number: (787) 622-5151 ext. #7633

Mobil Telephone Number: (787) 518-3739

5.2.2 Responsibilities of the Emergency Response Coordinators

The Emergency Response Coordinators are the designated persons responsible for carrying out the emergency response procedures during an ETO release/leak or Diesel oil spill. The following are their responsibilities:

- Determine the actual emergency or equipment malfunction,
- Activate the internal alarms of the facility, if not already started,
- Notify the appropriate local authorities of the emergency,
- Take reasonable steps to bring emergencies under control,
- Coordinate the clean up and disposal procedures,
- Activate Out-side Contractors to assist in the Emergency,
- Submit reports to the local regulatory agencies, and
- Review the taken actions, and if necessary, prepare amendments to this Emergency Plan

The emergency coordinators will also insure that the emergency crew will restore all emergency equipment to full operating status.

Once the emergency incident is under control, the Emergency Coordinators, supervisors and/or out-side contractors will initiate the cleaning-up and the reclamation activities of the affected area. The activities must be based on:

- Safety of people in the affected working area,
- Safety of environmental impact of upwind/downwind neighbors,
- Safety of property and materials in the area, and
- Regulatory Considerations

The Emergency Coordinators and plant supervisors will immediately investigate the cause of the emergency. They will take the necessary steps to prevent the incident from reoccurring.



5.2.3 CUSTOMED Administrative Procedures

CUSTOMED has to alert and notify such emergency to the appropriate government agencies. The EQB will be immediately alerted of such failure. CUSTOMED will alert any of the government agencies listed in the above EMERGENCY TELEPHONE NUMBERS.

The Coordinators should provide all the pertinent available facts, including an estimate of the incident duration and the amount of hazardous substance released or spilled to the local ambient.

5.2.3.1 Initial Telephone Notification

Once the Emergency Response Coordinators have corroborated the incidental emission, release or leak of hazardous substance, CUSTOMED must have available the following verbal information:

- a. The name of the reporter and his (her) telephone number,
- b. The affected process equipment,
- c. Date, Time and Duration of the Incident,
- d. Causes of the Incident,
- c. Quantity of hazardous substance involved, to the extent known,
- d. The extent of injuries, if any,
- e. The hazards to the human health or the environment, and
- f. The correctives measure taken or to be taken

5.2.3.2 Written Report

The following regulatory government agency must be contacted by both, telephone and written report of emergencies:

Amalrilys Rosario Carolina LEPC Environmental Emergencies Division PR-Environmental Quality Board (EQB) P.O. Box 11488, San Juan, PR zip: 00910 Tel. (787) 767-8181 ext. 3228, 3231, 3248, 6141

The Emergency Response Coordinators must note in the operating records the time, date and details of the incident that requires the carrying out of the Human Evacuation Plan. Within one week after the incident, the Emergency Coordinators must submit a written report of



the incident to the EQB. At least, the report must include the following information:

- 1. A certification that the malfunction or emergency has been corrected, specifying the date of correction and proof of compliance,
- 2. A description of the corrective measures undertaken to avoid such hazardous substance incidents in the future,
- 3. An estimate of the total emission caused by such incidental emission, release or leak of hazardous substance, and
- 4. Photographs of the equipment or controls that failed, whenever available.



SECTION VI: DETECTION INSTRUMENT FOR HAZARDOSUS SUBSTANCES

The Rule 107 (C) (j) of the EQB regulation requires the identification of equipment, instrument or measure that are or will be available in the facility to detect any emission, release or leak of hazardous substance.

ETO is a colorless gas at standard conditions, which has sweet, olefinic/ether-like odor that it is easily to perceive at low concentrations.

6.1 ETO Leak Detection Instruments

CUSTOMED also operate as a prevention and counter measure a Low Explosive Level Sensor (LEL-Sensors) for measurement the ETO concentrations at the following sites:

- A. Inside the room of the Sterilization Chamber,
- B. Inside of one of the ETO-Cylinder Room and
- C. At the Packed Venturi-Scrubber

The LEL-Sensor System operates on a continuous mode without interruption. The system calibration is performed on an annual basis by the vendor's technicians.

The Sensor System is capable to shut down automatically the sterilization process, if a release/leak of ETO is detected. If the System is activated for any reason, the gases in the sterilization chamber are automatically evacuated to the Packed Venturi-Scrubber as a safe prevention and counter measure. The evacuation objective is to avoid an ETO emergency. Appendix H provides literature of the manufacturer of the LEL-Sensor System.

CUSTOMED also relies on the Pressure/Vacuum System of the sterilization chamber; e.g. where potential ETO resides. If the System is activated, the reason could be an ETO leaking problem. The chamber will immediately initiate the ETO evacuation to the Packed Venturi-Scrubber.

6.2 Diesel Oil Leak Detection Instruments

CUSTOMED employees perform visual checks of the pipelines, unions, valves and the storage tank in Diesel Oil service. The tanks and all its appurtenances are above ground.

The 5,000 gallons Tank is provided with an audible alarm. The audible alarm is activated if the liquid level in the tank exceeds the setting during its filling up activity. Appendix I provides literature of the manufacturer.

SECTION VII: HUMAN EVACUATION PROCEDURE

The Rule 107 (C) (2) (k) of the EQB regulation requires a description of the human evacuation procedures in case of an emergency.

Although our Diesel tank has a maximum capacity of 5,000 gallons, the normal storing capacity is 4,500 gallons. The worst scenario of an emergency of hazardous substances here is a release or leak of gaseous ETO.

However, events of ETO-releases/leaks and/or Diesel oil spills near the amounts listed on Table #1 will require that the Emergency Response Coordinators consider the employees evacuation. Specifically, the employees who work in the Process Building where are located the sterilization chamber, the acid-water Packed Venturi-Scrubber, the aeration room and the ETO-Cylinder Room. Notice in Figure 2 that the Diesel Tank is in the premises of the Building, too.

CUSTOMED already has a sound alarm in the process building and in the administration facility. CUSTOMED will also provide in the plant a fabric/vinyl wind direction device, at about 10 feet above the Process Building. The objective is to know the actual wind direction in the event of an emergency of hazardous substances.

Appendix J provides new details of the alert and evacuation procedures. Events that require our employees' evacuation from the Process Building and the Administrative Building will follow the procedure in the Attachment during an emergency alert. Notice, Figure #2 also provides the locations of rally points. Figure #3 provides a description of the zone classification of the neighborhood near the CUSTOMED site.



SECTION VIII: DISPOSAL OF HAZARDOUS MATERIAL

The Rule 107 (C)(2)(I) of the EQB regulation requires the identification of methods to dispose materials that may produce emissions, releases or leaks of Ethylene Oxide; or a preventing measure.

After an emergency of ETO-release/leak or a Diesel oil spill is in control, the Emergency Response Team (ER-Team) will inspect and assess the areas of the affected building and its near physical facilities. The Team will check rooms, enclosed areas and the premises of the process and administrative buildings. The objective is to find out the following:

- 1.) Assess the physical conditions of the units listed in Table #2 and #3,
- 2.) Check enclosed areas or rooms where residue or deposit of hazardous substance still may be present

The ER-Coordinators together with the supervisors of the affected working area will determine the best course of action to accomplish the cleaning-up activity. An out side contractor with the appropriate qualifications will be hired to accomplish both, (1)-all the cleaning-up activity and (2)-the disposal of hazardous materials.

8.1 Disposal Method of Hazardous Substances

After the cleaning-up activity, the following is the method to dispose any hazardous substance:

- 8.1.1 All persons who had in contact with hazardous substance emergency will be required to decontaminate themselves and their equipment before leaving the affected area. Procedures for decontamination can be as simple as removing disposable protective equipment.
- 8.1.2 All decontamination procedures will be outlined by the Emergency Response Coordinators and the hired contractor. All discarded protective equipment, washing water and rinse water, is assumed to be contaminated and should be disposed accordingly.
- 8.1.3 Clean up during emergencies will vary due to the involved circumstances. Any clean up residues that contain known hazardous substance are classified as a hazardous waste and, therefore, must be handled properly. Efforts should be made to reduce the generation of extra clean up materials.
- 8.1.4 Any recovered waste generated during a hazardous substance emergency will be treated, stored and disposed according to the environmental regulations.



8.1.5 Any affected defective unit listed in Tables #2 and #3 will be disposed as a hazardous material. The ER-Coordinators will require that the a qualified contractor accomplish any disposal of materials according to the environmental procedures of both, the PR-Environmental Quality Board (EQB) and/or the US-Environmental Protection Agency (EPA).

Any residue or deposit of hazardous substances is found in any enclosed area, rooms or pockets, the ER-Coordinator will require the contractor to proceed to clean up the affected site. The contractor will use set up any of the following devices to accomplish the clean up pockets of hazardous substance:

- A.) Air movers (large fans) for gas hazardous substance, or
- B.) Suction pumps and storage drums for liquid hazardous substance



SECTION IX: MITIGATION OF PERSISTING IMPACT TO THE ENVIRONMENT

The Rule 107 (C) (2) (m) of the EQB regulation requires the identification of methods or procedures to mitigate persisting impact to the environment, after the health and welfare of humans have been safeguarded.

CUSTOMED INC. has identified that the persisting impact to the environment, could be the presence of moderate releases/leaks or spills of the affected hazardous substance. This means that the emergency episode is not in full control.

CUSTOMED may require the replacement or re-build of the following defective items, which were in hazardous substance service at the time of the emergency episode:

- (1) Process equipment,
- (2) Storage cylinders
- (3) Storage Tank
- (4) Processing Rooms
- (5) Process pipelines, others
- 9.1 Mitigation Procedure of a Hazardous Substance

To mitigate persisting impact to the environment due to a hazardous substance release/leak or spill, the ER-Coordinators will conduct the following procedure:

- 9.1.1 Hire an out side contractor to find out the source of the persisting impact of the affected hazardous substance in the environment. The contractor should commence with the five listed items above; e.g. equipment, rooms, cylinders, tank and pipelines.
- 9.1.2 The ER-Coordinators must be informed of the reason of the persisting impact, and whether the hazardous substance release/leak or spill can be controlled by any normal procedure with the equipment at hand. A normal procedure could be as simple as closing any valve to mitigate the release/leak or spill.

CUSTOMED has determine that any persisting impact of ETO or Diesel oil in the environment must be mitigated by an out side professional contractor who is already trained and has the capability to deal with this kind of job.

CUSTOMED will required that the hired professional contractor has the appropriate safety/protection equipment for hazardous substance and its personnel have the appropriate training, equipment and leak-instrumentation.



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SECTION X: EMERGENCY RESPONSES TEAM (ER-Team)

The Rule 107 (C)(2)(n) of the EQB regulation requires a description of the response team members and other involved personnel knowledgeable and trained in emergency response duties.

The Emergency Response Team (ER-Team) only consists of the knowledgeable CUSTOMERD's employees and/or plant operators who are familiar with the daily operation of their process equipment in ETO and/or Diesel Oil services. The Emergency Coordinators activate the team members according to the necessary efforts to control any release/leak or spill of an emergency of hazardous substances.

10.1 Description of the Emergency Response Team:

The Emergency Response Team includes the following personnel.

- a. Mr. Elvin Almodóvar,
- b. Mr. Héctor Agosto,
- c. Mr. Juan Carlos Pacheco, and
- d. Mr. Fernando Ruiz

10.2 Training of the ER-Team:

A training program has been established to familiarize the team members in emergency procedures. The new employees are also instructed in the proper operation and maintenance of the equipment in ETO and Diesel Oil services.

10.2.1 Personnel Training Requirement

The personnel involved in the management and handling of emergencies of hazardous substances must attend to periodic training programs. Qualified Consultants conduct the training program. The training involves both, a general and a detailed discussion of the management of incidental releases, leaks and spills of hazardous substances.

At least, the following issues are discussed in the general training program:

- 1. Discussion of the Applicable Laws,
- 2. The Ethylene Oxide/Diesel Oil Hazards to Personnel,
- 3. The Ethylene Oxide/Diesel Oil Problems in Properties and the Environment,
- 4. Object of the Emergency Response Plan (EQB-Rule 107–C)
- 5. Functions of the Emergency Response Coordinators,



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- 6. Responsibilities of Emergency Response Team, and
- 7. The General Response Procedure for Releases of Hazardous Substances in the Environment

The training should be specifically structured, and it will also include:

- 1. The responsibilities of the person who attends the training,
- 2. The response procedures to be followed in case of emergencies,
- 3. The location and use of the emergency response equipment, and
- 4. Potential health and fire hazards associated a with response activity.

10.2.2 Training Key Features

The Training Program includes the following key features:

- 1. Health effects of exposure to ETO/Diesel Oil or hazardous substances,
- 2. Applicable first aid procedures to be used following exposure,
- 3. Requirement of the protective equipment and procedures for using it,
- Human Evacuation Procedures.
- 5. Applicable fire fighting procedures and special hazards of ETO/Diesel Oil,
- 6. Reactivity of ETO/Diesel Oil with common materials,
- 7. Location of posted copies of the Emergency Response Plan,
- 8. The many aspects of visual inspection associated with the working areas.

10.2.3 Schedules of the Training Program

CUSTOMED is concerned about well trained employees and plant operators in issues of releases/leaks of ETO and Diesel Oil spills. The personal protection of the ER-Team is also required to control an emergency of hazardous substance in the premises of the plant. The training sessions will offer to the attendants the opportunity to openly discuss and analyze previous experiences and/or improvements that CUSTOMED could implement in the plant to reduce emergency episodes of hazardous substances. Therefore, the schedule of the training program is the following:

- 1. Six (6) months after a new personnel starts in a position as "Supervisor",
- 2. After any significant revision to the Emergency Response Plan,
- 3. After an emergency in which training deficiencies were noted, and
- 4. When the Emergency Response Coordinators find out a necessity

10.2.4 Contractors' Responsibilities

Any suppliers and contractors will be advised about the CUSTOMED policy for the delivering or handling of hazardous substances (ETO/Diesel Oil) in the premises of the plant.

Any hired Contractor will be informed about his (her) responsibility to have well trained personnel to perform duties related with emergencies of hazardous substance release/leak or spills. The contractor must supply the necessary personal protection and training to his employees.